

## **RESOLUTIONS**

### **EB134.R1      Appointment of the Regional Director for South-East Asia**

The Executive Board,

Considering the provisions of Article 52 of the Constitution of the World Health Organization;

Considering also the nomination made by the Regional Committee for South-East Asia at its sixty-sixth session,

1. APPOINTS Dr Poonam Khetrapal Singh as Regional Director for South-East Asia as from 1 February 2014;
2. AUTHORIZES the Director-General to issue to Dr Poonam Khetrapal Singh a contract for a period of five years from 1 February 2014 subject to the provisions of the Staff Regulations and Staff Rules;
3. AUTHORIZES the Director-General to amend the conditions of employment of Dr Poonam Khetrapal Singh as follows: “You will not participate in the United Nations Joint Staff Pension Fund but will instead receive as a monthly supplement the contribution that the Organization would have paid each month to the Pension Fund had you been a participant”.

(Third meeting, 21 January 2014)

### **EB134.R2      Expression of appreciation to Dr Samlee Plianbangchang**

The Executive Board,

Desiring, on the occasion of the retirement of Dr Samlee Plianbangchang as Regional Director for South-East Asia, to express its appreciation of his services to the World Health Organization;

Mindful of his lifelong devotion to the cause of international health, and especially recalling his 10 years of service as Regional Director for South-East Asia;

Recalling resolution SEA/RC66/R2, adopted by the Regional Committee for South-East Asia, which designates Dr Samlee Plianbangchang as Regional Director Emeritus of the World Health Organization,

1. EXPRESSES its profound gratitude and appreciation to Dr Samlee Plianbangchang for his invaluable contribution to the work of WHO;
2. ADDRESSES to him on this occasion its sincere good wishes for many further years of service to humanity.

(Third meeting, 21 January 2014)

**EB134.R3      Appointment of the Regional Director for the Western Pacific**

The Executive Board,

Considering the provisions of Article 52 of the Constitution of the World Health Organization;

Considering also the nomination made by the Regional Committee for the Western Pacific at its sixty-fourth session,

1. REAPPOINTS Dr Shin Young-soo as Regional Director for the Western Pacific as from 1 February 2014;
2. AUTHORIZES the Director-General to issue to Dr Shin Young-soo a contract for a period of five years from 1 February 2014 subject to the provisions of the Staff Regulations and Staff Rules;
3. AUTHORIZES the Director-General to amend the conditions of employment of Dr Shin Young-soo as follows: “You will not participate in the United Nations Joint Staff Pension Fund but will instead receive as a monthly supplement the contribution that the Organization would have paid each month to the Pension Fund had you been a participant”.

(Third meeting, 21 January 2014)

**EB134.R4      Global strategy and targets for tuberculosis prevention, care and control after 2015**

The Executive Board,

Having considered the report on the proposed global strategy and targets for tuberculosis prevention, care and control after 2015,<sup>1</sup>

RECOMMENDS to the Sixty-seventh World Health Assembly the consideration and adoption of the following resolution:<sup>2</sup>

The Sixty-seventh World Health Assembly,

Having considered the report on the draft global strategy and targets for tuberculosis prevention, care and control after 2015;

Acknowledging the progress made towards the achievement of Millennium Development Goal 6 (Combat HIV/AIDS, malaria and other diseases) for 2015 following the United Nations Millennium Declaration and related 2015 tuberculosis targets, through the adoption of the DOTS strategy, the Stop TB Strategy and the Global Plan to Stop TB 2006–2015, as well as the financing of national plans based on those frameworks, as called for, inter alia, in resolution WHA60.19 on tuberculosis control;

Concerned by the persisting gaps and the uneven progress made towards current targets, and in addition that some regions, Member States, communities and vulnerable groups require

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<sup>1</sup> Document EB134/12.

<sup>2</sup> See Annex 5 for the financial and administrative implications for the Secretariat of the adoption of the resolution.

specific strategies and support to accelerate progress in preventing disease and deaths, and to expand access to needed interventions and new tools;

Further concerned that even with significant progress, an estimated three million people who contract tuberculosis each year will not have their disease detected or will not receive appropriate care and treatment;

Cognizant of the serious economic and social consequences of tuberculosis and of the burden borne by many of those affected when seeking care and adhering to tuberculosis treatment;

Considering resolution WHA62.15 on prevention and control of multidrug-resistant tuberculosis and extensively drug-resistant tuberculosis, and its appeal for action; aware that the response to the crisis to date has been insufficient despite the introduction of new rapid diagnostic tests and efforts to scale up disease management; aware also that the vast majority of those in need still lack access to high-quality prevention, treatment and care services; and alarmed at the grave individual and public health risks posed by multidrug-resistant tuberculosis;

Aware that HIV coinfection is the main reason for the failure to meet tuberculosis control targets in high-HIV prevalence settings and that tuberculosis is a major cause of deaths among people living with HIV, and recognizing the need for substantially enhanced joint action in addressing the dual epidemics of tuberculosis and HIV/AIDS through increasing integration of primary care services in order to improve access to care;

Recognizing that further progress on tuberculosis and other health priorities identified in the United Nations Millennium Declaration must be made in the decades beyond 2015, and that progress on all of those priorities requires overall commitment to health system strengthening and progress towards universal health coverage;

Acknowledging that progress against tuberculosis depends on action within and beyond the health sector in order to address the social and economic determinants of disease, including expansion of social protection and overall poverty reduction;

Guided by resolution WHA61.17 on the health of migrants and its appeal for action, and recognizing the need for increased collaboration between high- and low-incidence countries and regions in strengthening tuberculosis monitoring and control mechanisms, including with regard to the growing mobility of labour;

Noting the need for increased investment in accelerated implementation of innovations at country level as well as in the research and development of new tools for tuberculosis care and prevention that are essential for the elimination of tuberculosis,

1. ADOPTS the global strategy and targets for tuberculosis prevention, care and control after 2015 with:

- (1) its bold vision of a world without tuberculosis, and its targets of ending the global tuberculosis epidemic by 2035 through a reduction in tuberculosis deaths by 95% and in tuberculosis incidence by 90% (or to fewer than 10 tuberculosis cases per 100 000 population), and elimination of associated catastrophic costs for tuberculosis-affected households;
- (2) its associated milestones for 2020, 2025 and 2030;

- (3) its principles addressing: government stewardship and accountability; coalition-building with affected communities and civil society; equity, human rights and ethics; and adaptation to fit the needs of each epidemiological, socioeconomic and health system context;
  - (4) its three pillars of: integrated, patient-centred care and prevention; bold policies and supportive systems; and intensified research and innovation;
2. URGES all Member States:<sup>1</sup>
- (1) to adapt the strategy;
  - (2) to implement, monitor and evaluate the strategy's proposed tuberculosis-specific health sector and multisectoral actions with high-level commitment and adequate financing, taking into account the local settings;
  - (3) to seek, with the full engagement of a wide range of stakeholders, to prevent the persistence of high incidence rates of tuberculosis within specific communities or geographical settings;
3. INVITES international, regional, national and local partners from within and beyond the health sector to engage in, and support, the implementation of the strategy;
4. REQUESTS the Director-General:
- (1) to provide guidance to Member States on how to adapt and operationalize the strategy, including the promotion of cross-border collaboration to address the needs of vulnerable communities and the threats posed by drug resistance;
  - (2) to coordinate and contribute to the implementation of the post-2015 global tuberculosis strategy, working with Member States, the Global Fund to Fight AIDS, Tuberculosis and Malaria, UNITAID and other global and regional financing institutions, as well as all constituencies of the Stop TB Partnership and the additional multisectoral partners required to achieve the goal and objectives of the strategy;
  - (3) to further develop and update global normative and policy guidance on tuberculosis prevention, care and control, as new evidence is gathered and innovations are developed, adding to the tools and strategic approaches that are available for ending the global epidemic and moving far more rapidly towards tuberculosis elimination;
  - (4) to support Member States upon request in the adaptation and implementation of the strategy, as well as in the development of nationally appropriate indicators, milestones and targets to contribute to local and global achievement of the 2035 target;
  - (5) to monitor the implementation of the strategy, and evaluate impact in terms of progress towards set milestones and targets;
  - (6) to promote the research and knowledge generation required to end the global tuberculosis epidemic and eliminate tuberculosis, including accelerated discovery and

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<sup>1</sup> And, where applicable, regional economic integration organizations.

development of new or improved diagnostics, treatment and preventive tools, in particular efficient vaccines, and the stimulation of the uptake of resulting innovations;

(7) to promote equitable access to new tools and medical products for the prevention, diagnosis, and treatment of tuberculosis and multidrug-resistant tuberculosis as they become available;

(8) to work with the Stop TB Partnership, including active support of the development of the global investment plan, and, where appropriate, seeking out new partners who can leverage effective commitment and innovation within and beyond the health sector in order to implement the strategy effectively;

(9) to report on the progress achieved to the Seventieth and Seventy-third World Health Assemblies, and at regular intervals thereafter, through the Executive Board.

(Fourth meeting, 21 January 2014)

**EB134.R5      Public health impacts of exposure to mercury and mercury compounds: the role of WHO and ministries of public health in the implementation of the Minamata Convention**

The Executive Board,

Having considered the report on public health impacts of exposure to mercury and mercury compounds: the role of WHO and ministries of public health in the implementation of the Minamata Convention,<sup>1</sup>

RECOMMENDS to the Sixty-seventh World Health Assembly the adoption of the following resolution:<sup>2</sup>

The Sixty-seventh World Health Assembly,

Having considered the report on public health impacts of exposure to mercury and mercury compounds: the role of WHO and ministries of public health in the implementation of the Minamata Convention;

Recalling World Health Assembly resolutions WHA60.17 on oral health: action plan for promotion and integrated disease prevention, WHA63.25 on the improvement of health through safe and environmentally sound waste management, and WHA59.15 on the Strategic Approach to International Chemicals Management, as well as the strategy for strengthening the engagement of the health sector in the implementation of the strategic approach adopted by the International Conference on Chemicals Management at its third session;

Recognizing the importance of dealing effectively with the health aspects of the challenges that chemicals and wastes, including mercury, may pose, particularly to vulnerable populations, especially women, children, and, through them, future generations;

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<sup>1</sup> Document EB134/23.

<sup>2</sup> See Annex 5 for the financial and administrative implications for the Secretariat of the adoption of the resolution.

Recalling the renewed commitments on sustainable development set out in the United Nations Conference on Sustainable Development Rio+20 outcome document “The future we want”, of June 2012, as well as the Adelaide Statement on Health in All Policies of 2010, and the 8th Global Conference on Health Promotion, held in Helsinki in 2013, which promoted intersectoral collaboration across all sectors to achieve healthy populations;

Taking note that negotiations on the text of a new multilateral environmental agreement on mercury were concluded in October 2013 with the adoption of the Minamata Convention on Mercury, being the first time that a multilateral environmental agreement includes a specific article on health, as well as other relevant provisions, and that the Convention places certain obligations on Parties that will require action, as applicable, by the health sector, together with other competent sectors, including the progressive phase-out, resulting from banning the manufacture, import or export by 2020 of mercury thermometers and sphygmomanometers, of mercury-containing cosmetics, including skin-lightening soaps and creams, and mercury-containing topical antiseptics, measures to be taken to phase down mercury-added dental amalgam, and the development of public health strategies on the exposure to mercury of artisanal and small-scale gold miners and their communities;

Recalling that the objective of the Minamata Convention on Mercury is to protect human health and the environment from anthropogenic emissions and releases of mercury and mercury compounds;

Bearing in mind that the Minamata Convention on Mercury encourages Parties to: (a) promote the development and implementation of strategies and programmes to identify and protect populations at risk, particularly vulnerable populations, and which may include adopting science-based health guidelines relating to the exposure to mercury and mercury compounds, setting targets for mercury exposure reduction, where appropriate, and public education, with the participation of public health and other involved sectors; (b) promote the development and implementation of science-based educational and preventive programmes on occupational exposure to mercury and mercury compounds; (c) promote appropriate health care services for prevention, treatment and care for populations affected by the exposure to mercury or mercury compounds; and (d) establish and strengthen, as appropriate, the institutional and health professional capacities for the prevention, diagnosis, treatment and monitoring of health risks related to the exposure to mercury and mercury compounds;

Noting that the Minamata Convention on Mercury states that the Conference of the Parties, in considering health-related activities, should consult, collaborate and promote cooperation and exchange of information with WHO, ILO and other relevant intergovernmental organizations, as appropriate;

Thanking the Secretariat for its preparatory work, during the negotiations, analysing different risks and available substitutes, as well as analysing and identifying areas requiring additional or new effort, under the Minamata Convention, and encouraging further and continuous analysis and other efforts as may be needed,

1. WELCOMES the formal adoption by Parties of the Minamata Convention on Mercury in October 2013;

2. ENCOURAGES Member States:<sup>1</sup>

- (1) to take the necessary domestic measures promptly to sign, ratify and implement the Minamata Convention on Mercury, which sets out internationally legally binding measures to address the risks of mercury and mercury compounds on human health and the environment;
- (2) to participate actively in national, regional and international efforts to implement the Minamata Convention on Mercury;
- (3) to address the health aspects of exposure to mercury and mercury compounds in the context of their health sector uses, and also the other negative health impacts that should be prevented or treated, by ensuring the sound management of mercury and mercury compounds throughout their life cycle;
- (4) to recognize the interrelation between the environment and public health in the context of the implementation of the Minamata Convention on Mercury and sustainable development;
- (5) to promote appropriate health care services for prevention, treatment and care for populations affected by the exposure to mercury or mercury compounds, including effective risk communication strategies targeted at vulnerable groups, such as children and women of childbearing age, especially pregnant women;
- (6) to ensure close cooperation between ministries of health and ministries of environment, as well as ministries of labour, industry, economy, agriculture and other ministries responsible for the implementation of aspects of the Minamata Convention on Mercury;
- (7) to facilitate the exchange of epidemiological information concerning health impacts associated with exposure to mercury and mercury compounds, in close cooperation with WHO and other relevant organizations, as appropriate;

3. REQUESTS the Director-General:

- (1) to facilitate WHO's efforts to provide advice and technical support to Member States to support the implementation of the Minamata Convention on Mercury in all health aspects related to mercury, consistent with WHO's programme of work, in order to promote and protect human health;
- (2) to provide support to Member States in developing and implementing strategies and programmes to identify and protect populations at risk, particularly vulnerable populations, which may include adopting science-based health guidelines relating to exposure to mercury and mercury compounds, setting targets for mercury exposure reduction, where appropriate, and public education, with the participation of health and other involved sectors;

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<sup>1</sup> And, where applicable, regional economic integration organizations.

(3) to cooperate closely with the Minamata Convention Intergovernmental Negotiating Committee, the Conference of the Parties and other international organizations and bodies, mainly UNEP, to fully support the implementation of the health-related aspects of the Minamata Convention on Mercury and to provide information to the Committee and Conference of the Parties on the progress made in this regard.

(Eighth meeting, 23 January 2014)

## **EB134.R6      Traditional medicine**

The Executive Board,

Having considered the report on traditional medicine,<sup>1</sup>

RECOMMENDS to the Sixty-seventh World Health Assembly the adoption of the following resolution:<sup>2</sup>

The Sixty-seventh World Health Assembly,

Having considered the report on traditional medicine;

Recalling resolutions WHA22.54, WHA29.72, WHA30.49, WHA31.33, WHA40.33, WHA41.19, WHA42.43, WHA44.34, WHA54.11, WHA56.31, WHA61.21, and in particular WHA62.13 on traditional medicine, which requested the Director-General, inter alia, to update the WHO traditional medicine strategy 2002–2005, based on countries' progress and current new challenges in the field of traditional medicine;

Affirming the growing importance and value of traditional and complementary medicine in the provision of health care nationally and globally, and that such medicines are no longer limited exclusively to any particular regions or communities;

Noting the heightened level of interest in aspects of traditional and complementary medicine practices and in their practitioners, and related demand from consumers and governments that consideration be given to integration of those elements into health service delivery;

Noting also that the major challenges to the area of traditional and complementary medicine include deficiencies in: knowledge-based management and policy; appropriate regulation of practices and practitioners; monitoring and implementation of regulation on products; and appropriate integration of traditional and complementary medicine services into health care service delivery and self-health care,

1. TAKES NOTE of the WHO traditional medicine strategy: 2014–2023, its three objectives, and the relevant strategic directions and strategic actions that guide the traditional medicine sector in its further development and advancement over the next decade;

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<sup>1</sup> Document EB134/24.

<sup>2</sup> See Annex 5 for the financial and administrative implications for the Secretariat of the adoption of the resolution.



2. URGES Member States, in accordance with national capacities, priorities, relevant legislation and circumstances:

- (1) to adopt, adapt and implement, where appropriate, the WHO traditional medicine strategy: 2014–2023 as a basis for national traditional and complementary medicine programmes or work plans;
- (2) to report to WHO on progress in implementing the WHO traditional medicine strategy: 2014–2023;

3. REQUESTS the Director-General:

- (1) to facilitate Member States' implementation of the WHO traditional medicine strategy: 2014–2023, supporting their formulation of related knowledge-based national policies, standards and regulations, and strengthening national capacity-building accordingly through information sharing, networks and training workshops;
- (2) to continue to provide policy guidance to Member States on how to integrate traditional and complementary medicine services within their national and/or subnational health care system(s), as well as the technical guidance that would ensure the safety, quality and effectiveness of such traditional and complementary medicine services;
- (3) to continue to promote international cooperation and collaboration in the area of traditional and complementary medicine in order to share evidence-based information, taking into account the traditions and customs of indigenous peoples and communities;
- (4) to monitor the implementation of the WHO traditional medicine strategy: 2014–2023;
- (5) to report to the Seventy-second World Health Assembly, through the Executive Board, on progress made in implementing this resolution.

(Eighth meeting, 23 January 2014)

**EB134.R7      Strengthening of palliative care as a component of integrated treatment within the continuum of care**

The Executive Board,

Having considered the report on strengthening of palliative care as a component of integrated treatment throughout the life course,<sup>1</sup>

RECOMMENDS to the Sixty-seventh World Health Assembly the adoption of the following resolution:<sup>2</sup>

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<sup>1</sup> Document EB134/28.

<sup>2</sup> See Annex 5 for the financial and administrative implications for the Secretariat of the adoption of the resolution.

The Sixty-seventh World Health Assembly,

Having considered the report on strengthening of palliative care as a component of integrated treatment throughout the life course;

Recalling resolution WHA58.22 on cancer prevention and control, especially as it relates to palliative care;

Taking into account the United Nations Economic and Social Council's Commission on Narcotic Drugs' resolutions 53/4 and 54/6 respectively entitled "Promoting adequate availability of internationally controlled licit drugs for medical and scientific purposes while preventing their diversion and abuse" and "Promoting adequate availability of internationally controlled narcotic drugs and psychotropic substances for medical and scientific purposes while preventing their diversion and abuse";

Acknowledging the special report of the International Narcotics Control Board on the availability of internationally controlled drugs: ensuring adequate access for medical and scientific purposes,<sup>1</sup> and the WHO guidance on ensuring balance in national policies on controlled substances: guidance for availability and accessibility of controlled medicines;<sup>2</sup>

Also taking into account resolution 2005/25 of the United Nations Economic and Social Council on treatment of pain using opioid analgesics;

Bearing in mind that palliative care is an approach that improves the quality of life of patients (adults and children) and their families facing the problems associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and correct assessment and treatment of pain and other problems, whether physical, psychosocial or spiritual;

Recognizing that palliative care, when indicated, is fundamental to improving quality of life, well-being, comfort and human dignity for individuals, being an effective person-centred health service that values patients' need to receive adequate, personally and culturally sensitive information on their health status, and their central role in making decisions about the treatment received;

Affirming that access to palliative care and to essential medicines for medical and scientific purposes manufactured from substances under control, including opioid analgesics such as morphine, in line with the three United Nations international drug control conventions,<sup>3</sup> contributes to the realization of the right to the enjoyment of the highest attainable standard of health and well-being;

Acknowledging that palliative care is an ethical responsibility of health systems, and that it is the ethical duty of health care professionals to alleviate pain and suffering, whether physical, psychosocial or spiritual, irrespective of whether the disease or condition can be cured, and that end-of-life care for individuals is among the critical components of palliative care;

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<sup>1</sup> Document E/INCB/2010/1/Supp.1.

<sup>2</sup> Ensuring balance in national policies on controlled substances: guidance for availability and accessibility of controlled medicines. Geneva: World Health Organization; 2011.

<sup>3</sup> United Nations Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol; United Nations Convention on Psychotropic Substances, 1971; United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988.

Recognizing that more than 40 million people currently require palliative care every year, foreseeing the increased need for palliative care with ageing populations and the rise of noncommunicable and other chronic diseases worldwide, considering the importance of palliative care for children, and, in respect of this, acknowledging that Member States should have estimates of the quantities of the internationally controlled medicines needed, including medicines in paediatric formulations;

Realizing the urgent need to include palliation across the continuum of care, especially at the primary care level, recognizing that inadequate integration of palliative care into health and social care systems is a major contributing factor to the lack of equitable access to such care;

Noting that the availability and appropriate use of internationally controlled medicines for medical and scientific purposes, particularly for the relief of pain and suffering, remains insufficient in many countries, and highlighting the need for Member States, with the support of the WHO Secretariat, the United Nations Office on Drugs and Crime and the International Narcotics Control Board, to ensure that efforts to prevent the diversion of narcotic drugs and psychotropic substances under international control pursuant to the United Nations international drug control conventions do not result in inappropriate regulatory barriers to the medical access to such medicines;

Taking into account that the avoidable suffering of treatable symptoms is perpetuated by the lack of knowledge of palliative care, and highlighting the need for continuing education and adequate training for all hospital- and community-based health care providers and other caregivers, including nongovernmental organization workers and family members;

Recognizing the existence of diverse cost-effective and efficient palliative care models, acknowledging that palliative care uses an interdisciplinary approach to address the needs of patients and their families, and noting that the delivery of quality palliative care is most likely to be realized where strong networks exist between professional palliative care providers, support care providers (including spiritual support and counselling, as needed), volunteers and affected families, as well as between the community and providers of care for acute illness and the elderly;

Recognizing the need for palliative care across disease groups (noncommunicable diseases, and infectious diseases, including HIV and multidrug-resistant tuberculosis), and across all age groups;

Welcoming the inclusion of palliative care in the definition of universal health coverage and emphasizing the need for health services to provide integrated palliative care in an equitable manner in order to address the needs of patients in the context of universal health coverage;

Recognizing the need for adequate funding mechanisms for palliative care programmes, including for medicines and medical products, especially in developing countries;

Welcoming the inclusion of palliative care actions and indicators in the WHO comprehensive global monitoring framework for the prevention and control of noncommunicable diseases and in the global action plan for the prevention and control of noncommunicable diseases 2013–2020;

Noting with appreciation the inclusion of medicines needed for pain and symptom control in palliative care settings in the 18th WHO Model List of Essential Medicines and the 4th WHO Model List of Essential Medicines for Children, and commending the efforts of WHO collaborating centres on pain and palliative care to improve access to palliative care;

Noting with appreciation the efforts of nongovernmental organizations and civil society in continuing to highlight the importance of palliative care, including adequate availability and appropriate use of internationally controlled substances for medical and scientific purposes, as set out in the United Nations international drug control conventions;

Recognizing the limited availability of palliative care services in much of the world and the great avoidable suffering for millions of patients and their families, and emphasizing the need to create or strengthen, as appropriate, health systems that include palliative care as an integral component of the treatment of people within the continuum of care,

1. URGES Member States:<sup>1</sup>

(1) to develop, strengthen and implement, where appropriate, palliative care policies to support the comprehensive strengthening of health systems to integrate evidence-based, cost-effective and equitable palliative care services in the continuum of care, across all levels, with emphasis on primary care, community and home-based care, and universal coverage schemes;

(2) to ensure adequate domestic funding and allocation of human resources, as appropriate, for palliative care initiatives, including development and implementation of palliative care policies, education and training, and quality improvement initiatives, and support the availability and appropriate use of essential medicines, including controlled medicines for symptom management;

(3) to provide basic support, including through multisectoral partnerships, to families, community volunteers and other individuals acting as caregivers, under the supervision of trained professionals, as appropriate;

(4) to aim to include palliative care as an integral component of the ongoing education and training offered to care providers, in accordance with their roles and responsibilities, according to the following principles:

(a) basic training and continuing education on palliative care should be integrated as a routine element of all undergraduate medical and nursing professional education, and as part of in-service training of caregivers at the primary care level, including health care workers, caregivers addressing patients' spiritual needs and social workers;

(b) intermediate training should be offered to all health care workers who routinely work with patients with life-threatening illnesses, including those working in oncology, infectious diseases, paediatrics, geriatrics and internal medicine;

(c) specialist palliative care training should be available to prepare health care professionals who will manage integrated care for patients with more than routine symptom management needs;

(5) to assess domestic palliative care needs, including pain management medication requirements, and promote collaborative action to ensure adequate supply of essential medicines in palliative care, avoiding shortages;

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<sup>1</sup> And, where applicable, regional economic integration organizations.

(6) to review and, where appropriate, revise national and local legislation and policies for controlled medicines, with reference to WHO policy guidance,<sup>1</sup> on improving access to and rational use of pain management medicines, in line with the United Nations international drug control conventions;

(7) to update, as appropriate, national essential medicines lists, in the light of the recent addition of sections on pain and palliative care medicines to the WHO Model List of Essential Medicines and the WHO Model List of Essential Medicines for Children;

(8) to foster partnerships between governments and civil society, including patients' organizations, to support, as appropriate, the provision of services for patients requiring palliative care;

(9) to implement and monitor palliative care actions included in WHO's global action plan for the prevention and control of noncommunicable diseases 2013–2020;

2. REQUESTS the Director-General:

(1) to ensure that palliative care is an integral component of all relevant global disease control and health system plans, including those relating to noncommunicable diseases and universal health coverage, as well as being included in country and regional cooperation plans;

(2) to update or develop, as appropriate, evidence-based guidelines and tools on palliation, including pain management options, in adults and children, including the development of WHO guidelines for the pharmacological treatment of pain, and ensure their adequate dissemination;

(3) to develop and strengthen, where appropriate, evidence-based guidelines on the integration of palliative care into national health systems, across disease groups and levels of care, that adequately address ethical issues related to the provision of comprehensive palliative care, such as equitable access, person-centred and respectful care, and community involvement, and to inform education in pain and symptom management and psychosocial support;

(4) to continue, through WHO's Access to Controlled Medicines Programme, to support Member States in reviewing and improving national legislation and policies with the objective of ensuring balance between the prevention of misuse, diversion and trafficking of controlled substances and appropriate access to controlled medicines, in line with the United Nations international drug control conventions;

(5) to explore ways to increase the availability and accessibility of medicines used in palliative care through consultation with Member States and relevant networks and civil society, as well as other international stakeholders, as appropriate;

(6) to work with the International Narcotics Control Board, the United Nations Office on Drugs and Crime, health ministries and other relevant authorities in order to promote the availability and balanced control of controlled medicines for pain and symptom management;

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<sup>1</sup> Ensuring balance in national policies on controlled substances: guidance for availability and accessibility of controlled medicines. Geneva: World Health Organization; 2011.

(7) to further cooperate with the International Narcotics Control Board to support Member States in establishing accurate estimates in order to enable the availability of medicines for pain relief and palliative care, including through better implementation of the guidance on estimating requirements for substances under international control;<sup>1</sup>

(8) to collaborate with UNICEF and other relevant partners in the promotion and implementation of palliative care for children;

(9) to monitor the global situation of palliative care, evaluating the progress made in different initiatives and programmes in collaboration with Member States and international partners;

(10) to work with Member States to encourage adequate funding and improved cooperation for palliative care programmes and research initiatives, in particular in resource-poor countries, in line with the Programme budget 2014–2015, which addresses palliative care;

(11) to encourage research on models of palliative care that are effective in low- and middle-income countries, taking into consideration good practices;

(12) to report back to the Sixty-ninth World Health Assembly in 2016, through the Executive Board, on progress in the implementation of this resolution.

(Eighth meeting, 23 January 2014)

**EB134.R8      Contributing to social and economic development: sustainable action across sectors to improve health and health equity (follow-up of the 8th Global Conference on Health Promotion)**

The Executive Board,

Having considered the report on contributing to social and economic development: sustainable action across sectors to improve health and health equity (follow-up of the 8th Global Conference on Health Promotion),<sup>2</sup>

RECOMMENDS to the Sixty-seventh World Health Assembly the adoption of the following resolution:<sup>3</sup>

The Sixty-seventh World Health Assembly,

Having considered the report on contributing to social and economic development: sustainable action across sectors to improve health and health equity (follow-up of the 8th Global Conference on Health Promotion);

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<sup>1</sup> International Narcotics Control Board, World Health Organization. Guide on estimating requirements for substances under international control. New York: United Nations; 2012.

<sup>2</sup> Document EB134/54.

<sup>3</sup> See Annex 5 for the financial and administrative implications for the Secretariat of the adoption of the resolution.

Reaffirming the principles of the Constitution of the World Health Organization stating that governments have a responsibility for the health of their peoples which can be fulfilled only by the provision of adequate health and social measures;

Reaffirming the right of every human being without distinction of any kind to the enjoyment of the highest attainable standard of physical and mental health, and to a standard of living adequate for the health and well-being of oneself and one's family, including adequate food, clothing, housing and to the continuous improvement of living conditions;

Recalling the Declaration of Alma-Ata on Primary Health Care, 1978 and the Global Strategy of Health for All by the year 2000, and their calls for coordination, cooperation and intersectoral action for health;

Acknowledging the United Nations General Assembly document "The Future we want",<sup>1</sup> and in particular its recognition that health is a precondition for and an outcome and indicator of all three dimensions of sustainable development and the call for the involvement of all relevant sectors for coordinated multisectoral action to address urgently the health needs of the world's population;

Recalling World Health Assembly resolutions on health promotion, public information and education for health,<sup>2</sup> health promotion,<sup>3</sup> health promotion and healthy lifestyles,<sup>4</sup> health promotion in a globalized world,<sup>5</sup> and social determinants of health,<sup>6</sup> and taking note of the outcome documents of the seven global WHO conferences on health promotion,<sup>7</sup> in particular the Ottawa Charter, the Adelaide Statement and the Nairobi Call for Action;

Reaffirming commitments made to global health in the context of foreign policy and reiterating the request to consider universal health coverage in the discussions on the post-2015 development agenda, also considering broad public health measures, health protection and addressing determinants of health through policies across sectors;

Recalling the Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases<sup>8</sup> and the WHO global strategy and action plan on the prevention and control of noncommunicable diseases, which recognize the primary role of governments in responding to the challenge of noncommunicable diseases and the essential need for the efforts and engagement of all sectors, rather than by making changes in health sector policy alone, as well as the important role of the international community and international cooperation in assisting the Member States in these efforts;

Noting that the health sector has a key role in working with other sectors in ensuring drinking-water quality, sanitation, food and nutritional safety, air quality and limiting exposure

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<sup>1</sup> Annexed to United Nations General Assembly resolution 66/288.

<sup>2</sup> Resolution WHA42.44.

<sup>3</sup> Resolution WHA51.12.

<sup>4</sup> Resolution WHA57.16.

<sup>5</sup> Resolution WHA60.24.

<sup>6</sup> Resolution WHA65.8.

<sup>7</sup> Ottawa, 1986; Adelaide, Australia, 1988; Sundsvall, Sweden, 1991; Jakarta, 1997; Mexico City, 2000; Bangkok, 2005; Nairobi, 2009.

<sup>8</sup> Document A/66/L.1.

to health-damaging chemicals and radiation levels, as recognized in World Health Assembly resolutions;<sup>1</sup>

Recognizing that a number of mental disorders can be prevented and that mental health can be promoted in the health sector and in sectors outside health and that global support is necessary for national and local work on mental health and development, for instance through the Mental Health Action Plan and the WHO MINDbank;

Noting further the relevance of the WHO Framework Convention on Tobacco Control for many sectors, underscoring the importance of addressing common risk factors for noncommunicable diseases across sectors and the cooperation needs under the International Health Regulations (2005), including among the organizations in the United Nations system, and between and within Member States;

Acknowledging the final report of the Commission on Social Determinants and Health<sup>2</sup> as a source of evidence, as well as the Rio Political Declaration on Social Determinants of Health and its call for the development and implementation of robust, evidence-based, reliable measures of societal well-being, and recognizing the important advocacy role of health ministries in this regard;

Recognizing that Health in All Policies refers to taking the health implications of decisions systemically into account in public policies across sectors, seeking synergies and avoiding harmful health impacts, in order to improve population health and health equity through assessing the consequences of public policies on the determinants of health and well-being and on health systems;

Concerned about gaps in taking into account across government, at various levels of governance, the impacts of policies on health, health equity and the functioning of the health system,

1. NOTES with appreciation the Helsinki Statement on Health in All Policies, endorsed by the 8th Global Conference on Health Promotion, (Helsinki, 10–14 June 2013), and notes the ongoing work on the Health in All Policies Framework for Country Action;

2. URGES Member States:<sup>3</sup>

(1) to champion health and the promotion of health equity as a priority and take efficient action on social, economic and environmental determinants of health, consistent with resolution WHA65.8, including on noncommunicable disease prevention;

(2) to take steps, including, where appropriate, effective legislation, cross-sectoral structures, processes, methods and resources such as the Urban Health Equity Assessment and Response Tool, that enable societal policies which take into account and address their impacts on health determinants, health protection, health equity and health systems functioning, and which measure and track social determinants and disparities in health;

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<sup>1</sup> Resolutions WHA59.15, WHA61.19, WHA63.25, WHA63.26, WHA64.15, WHA64.24.

<sup>2</sup> World Health Organization. Commission on Social Determinants of Health. Closing the gap in a generation: health equity through action on the social determinants of health. Geneva: World Health Organization; 2008.

<sup>3</sup> And, where applicable, regional economic integration organizations.



(3) to develop, as appropriate, and maintain adequate and sustainable institutional capacity and skills, such as assessing health implications of policy initiatives in all sectors, exploring solutions and negotiating policies across sectors, including within health authorities and relevant research and development institutes such as national public health institutes, to achieve improved outcomes from the perspective of health, health equity and health systems functioning;

(4) to take action to enhance health and safeguard public health interests from undue influence by any form of real, perceived or potential conflict of interest, through managing risk, strengthening due diligence and accountability and increasing the transparency of decision-making and engagement;

(5) to include, as appropriate, relevant stakeholders such as local communities and civil society actors in the development, implementation and monitoring of policies across sectors;

(6) to contribute to development of the post-2015 development agenda by emphasizing that policies in sectors other than health have a significant impact on health outcomes, and by identifying synergies between health and other sector policy objectives;

3. REQUESTS the Director-General:

(1) to prepare, for the consideration of the Sixty-eighth World Health Assembly, in consultation with Member States,<sup>1</sup> United Nations organizations and other relevant stakeholders as appropriate, and within existing resources, a Framework for Country Action, for adaptation to different contexts, taking into account the Helsinki Statement on Health in All Policies, aimed at supporting national efforts to improve health, ensure health protection, health equity and health systems functioning, including through action across sectors on determinants of health and risk factors of noncommunicable diseases, based on best available knowledge and evidence;

(2) to provide guidance and technical assistance, upon request, to Member States in their efforts to build the necessary capacities, structures, mechanisms and processes in order to integrate health perspectives in non-health sector policies, including, where appropriate, through implementation of Health in All Policies, and for measuring and tracking social determinants and disparities in health;

(3) to strengthen WHO's role, capacities and knowledge resources, including by compiling and analysing good practices by Member States, to give guidance and technical assistance for implementation of policies across sectors at the various levels of governance, and ensure coherence and collaboration across programmes and initiatives within WHO;

(4) to continue to work with and provide leadership for the organizations in the United Nations system, development banks, other international organizations and foundations, in order to encourage them to take health considerations into account in major strategic initiatives and their monitoring, including the post-2015 development agenda, and to achieve coherence and synergy with commitments and obligations related to health and health determinants, including social determinants of health, in their work with Member States;

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<sup>1</sup> And, where applicable, regional economic integration organizations.

(5) to report on the progress made in implementing this resolution to the Sixty-ninth World Health Assembly through the Executive Board.

(Ninth meeting, 24 January 2014)

**EB134.R9 Confirmation of amendments to the Financial Rules**

The Executive Board

CONFIRMS, in accordance with Financial Regulation 16.1, the amendment to Financial Rule III that has been made by the Director-General, with immediate effect.<sup>1</sup>

(Tenth meeting, 23 January 2014)

**EB134.R10 Implementation of the International Health Regulations (2005)**

The Executive Board,

Having considered the report on implementation of the International Health Regulations (2005),<sup>2</sup>

RECOMMENDS to the Sixty-seventh World Health Assembly the adoption of the following resolution:<sup>3</sup>

The Sixty-seventh World Health Assembly,

Having considered the report on Implementation of the International Health Regulations (2005);

Recalling the recent meeting and report of the Strategic Advisory Group of Experts on immunization,<sup>4</sup> which completed its scientific review and analysis of evidence on issues concerning vaccination against yellow fever and concluded that a single dose of yellow fever vaccine is sufficient to confer sustained immunity and life-long protection against yellow fever disease, and that a booster dose of yellow fever vaccine is not needed;

Noting that in its report the Strategic Advisory Group of Experts on immunization recommended that WHO should revisit the provisions in the International Health Regulations (2005) relating to the period of validity for international certificates for vaccination against yellow fever,

1. ADOPTS, in accordance with paragraph 3 of Article 55 of the International Health Regulations (2005), the updated Annex 7 of the International Health Regulations (2005) below.

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<sup>1</sup> See Annex 1.

<sup>2</sup> Document EB134/32.

<sup>3</sup> See Annex 5 for the financial and administrative implications for the Secretariat of the adoption of the resolution.

<sup>4</sup> Meeting of the Strategic Advisory Group of Experts on immunization, April 2013 – conclusions and recommendations. Weekly epidemiological record. 2013;88(20):201–216.

**Proposed revisions to International Health Regulations (2005), Annex 7****ANNEX 7****REQUIREMENTS CONCERNING VACCINATION OR PROPHYLAXIS  
FOR SPECIFIC DISEASES**

1. In addition to any recommendation concerning vaccination or prophylaxis, the following diseases are those specifically designated under these Regulations for which proof of vaccination or prophylaxis may be required for travellers as a condition of entry to a State Party:

Vaccination against yellow fever.

2. Recommendations and requirements for vaccination against yellow fever:

(a) For the purpose of this Annex:

(i) the incubation period of yellow fever is six days;

(ii) yellow fever vaccines approved by WHO provide protection against infection starting 10 days following the administration of the vaccine;

(iii) this protection continues for the life of the person vaccinated ~~10 years~~; and

(iv) the validity of a certificate of vaccination against yellow fever shall extend for the life of the person vaccinated ~~a period of 10 years~~, beginning 10 days after the date of vaccination ~~or, in the case of a revaccination within such period of 10 years, from the date of that revaccination.~~

(b) Vaccination against yellow fever may be required of any traveller leaving an area where the Organization has determined that a risk of yellow fever transmission is present.

(c) If a traveller is in possession of a certificate of vaccination against yellow fever which is not yet valid, the traveller may be permitted to depart, but the provisions of paragraph 2(h) of this Annex may be applied on arrival.

(d) A traveller in possession of a valid certificate of vaccination against yellow fever shall not be treated as suspect, even if coming from an area where the Organization has determined that a risk of yellow fever transmission is present.

(e) In accordance with paragraph 1 of Annex 6 the yellow fever vaccine used must be approved by the Organization.

(f) States Parties shall designate specific yellow fever vaccination centres within their territories in order to ensure the quality and safety of the procedures and materials employed.

(g) Every person employed at a point of entry in an area where the Organization has determined that a risk of yellow fever transmission is present, and every member of the crew of a conveyance using any such point of entry, shall be in possession of a valid certificate of vaccination against yellow fever.

(h) A State Party, in whose territory vectors of yellow fever are present, may require a traveller from an area where the Organization has determined that a risk of yellow fever transmission is present, who is unable to produce a valid certificate of vaccination against yellow fever, to be quarantined until the certificate becomes valid, or until a period of not more than six days, reckoned from the date of last possible exposure to infection, has elapsed, whichever occurs first.

(i) Travellers who possess an exemption from yellow fever vaccination, signed by an authorized medical officer or an authorized health worker, may nevertheless be allowed entry, subject to the provisions of the foregoing paragraph of this Annex and to being provided with information regarding protection from yellow fever vectors. Should the travellers not be quarantined, they may be required to report any feverish or other symptoms to the competent authority and be placed under surveillance.

(Eleventh meeting, 24 January 2014)

### **EB134.R11 Confirmation of amendments to the Staff Rules**

The Executive Board,

Having considered the report on amendments to the Staff Regulations and Staff Rules, and the report of the Programme, Budget and Administrative Committee of the Executive Board,<sup>1</sup>

1. CONFIRMS, in accordance with Staff Regulation 12.2, the amendments to the Staff Rules that have been made by the Director-General with effect from 1 January 2014 concerning the remuneration of staff in the professional and higher categories, and with effect from the school year in progress on 1 January 2013 in respect of the level of the education grant;<sup>2</sup>
2. REQUESTS the Director-General to convey to the International Civil Service Commission (ICSC) and the United Nations General Assembly the views of WHO Member States that rising staff costs are having a considerable budgetary impact on the Organization and to request that the ICSC study the impact of their recommendations on the budgets of common system organizations, particularly within the context of their ongoing comprehensive compensation review.

(Eleventh meeting, 24 January 2014)

### **EB134.R12 Salaries of staff in ungraded posts and of the Director-General**

The Executive Board,

Having considered the report on amendments to the Staff Regulations and Staff Rules,<sup>3</sup>

RECOMMENDS to the Sixty-seventh World Health Assembly the adoption of the following resolution:<sup>4</sup>

The Sixty-seventh World Health Assembly,

Having considered the report on amendments to the Staff Regulations and Staff Rules;

Noting the recommendations of the Executive Board with regard to remuneration of staff in ungraded posts and of the Director-General,

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<sup>1</sup> Documents EB134/51 and EB134/3.

<sup>2</sup> See Annex 2 for the text of the amendments to the Staff Rules and Annex 5 for the financial and administrative implications for the Secretariat of the adoption of the resolution.

<sup>3</sup> Document EB134/51.

<sup>4</sup> See Annex 5 for the financial and administrative implications for the Secretariat of the adoption of the resolution.

1. ESTABLISHES the salaries of assistant directors-general and regional directors at US\$ 172 436 gross per annum with a corresponding net salary of US\$ 134 205 (dependency rate) or US\$ 121 527 (single rate);
2. ESTABLISHES the salary of the Deputy Director-General at US\$ 189 744 gross per annum with a corresponding net salary of US\$ 146 321 (dependency rate) or US\$ 131 682 (single rate);
3. ESTABLISHES the salary of the Director-General at US\$ 252 055 gross per annum with a corresponding net salary of US\$ 176 836 (dependency rate) or US\$ 157 262 (single rate);
4. DECIDES that those adjustments in remuneration shall take effect on 1 January 2014.

(Eleventh meeting, 24 January 2014)

### **EB134.R13      Combating antimicrobial resistance, including antibiotic resistance<sup>1</sup>**

The Executive Board,

Having considered the report on antimicrobial drug resistance,<sup>2</sup>

RECOMMENDS to the Sixty-seventh World Health Assembly the adoption of the following resolution:<sup>3</sup>

The Sixty-seventh World Health Assembly,

Having considered the report on antimicrobial drug resistance;

Recognizing WHO's leadership role in the containment of antimicrobial resistance;

Recalling resolutions WHA39.27 and WHA47.13 on the rational use of drugs, WHA51.17 on emerging and other communicable diseases: antimicrobial resistance, WHA54.14 on global health security, WHA58.27 on improving the containment of antimicrobial resistance, WHA60.16 on progress in the rational use of medicines and WHA66.22 on follow up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination;

Aware that access to effective antimicrobial agents constitutes a prerequisite for most of modern medicine, that hard-won gains in health and development, in particular those brought about through the health-related Millennium Development Goals, are at risk due to increasing resistance to antimicrobials, and that antimicrobial resistance threatens the sustainability of the public health response to many communicable diseases, including tuberculosis, malaria and HIV/AIDS;

Aware that the health and economic consequences of antimicrobial resistance constitute a heavy and growing burden on high-, middle- and low-income countries, requiring urgent action

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<sup>1</sup> Antimicrobial resistance refers to the loss of effectiveness of any anti-infective medicine, including antiviral, antifungal, antibacterial and antiparasitic medicines. Antibiotic resistance refers only to resistance to medicines in bacteria.

<sup>2</sup> Document EB134/37.

<sup>3</sup> See Annex 5 for the financial and administrative implications for the Secretariat of the adoption of the resolution.

at national, regional and global levels, particularly in view of the limited development of new antimicrobial agents;

Recognizing that the main impact of antimicrobial resistance is on human health, but that the contributing factors and consequences, including economic and others, go beyond health and therefore there is a need for a coherent, comprehensive and integrated approach at global, regional and national levels, in a “One Health” approach and beyond, involving different actors and sectors such as human and veterinary medicine, agriculture, environment and consumers;

Noting that awareness of the broad scope and urgency of the threat posed has been limited and that previous resolutions of the Health Assembly and WHO’s strategies for the containment of antimicrobial resistance have not yet been widely implemented;

Recognizing that antimicrobial resistance involves a wide range of pathogens including bacteria, viruses and parasites but that the development of resistance among some pathogens, particularly antibiotic-resistant bacteria, is of particular urgency and most in need of immediate attention;

Welcoming the establishment of the WHO Global Task Force on Antimicrobial Resistance and the tripartite collaboration between FAO, OIE and WHO,

1. URGES Member States:<sup>1</sup>

- (1) to increase political awareness, engagement and leadership in order to accelerate efforts to secure access to effective antimicrobials and to use them responsibly;
- (2) to take urgent action at national, regional and local levels to strengthen infection prevention and control, by means that include application of basic hygiene measures;
- (3) to develop or strengthen national plans and strategies and international collaboration for the containment of antimicrobial resistance;
- (4) to mobilize human and financial resources in order to implement plans and strategies to strengthen the containment of antimicrobial resistance;
- (5) to strengthen overall pharmaceutical management systems, including regulatory systems and supply chain mechanisms, and, where appropriate, laboratory infrastructure, with a view to ensuring access to and availability of effective antimicrobial agents, taking into account financial and other incentives that might have a negative impact on policies for prescribing and dispensing;
- (6) to monitor the extent of antimicrobial resistance and monitor regularly the use of antibiotics in all relevant sectors, in particular health and agriculture, including animal husbandry, and to share such information so national, regional and global trends can be detected and monitored;
- (7) to improve, among all relevant care providers, the public and other sectors and stakeholders, awareness of (i) the threat posed by antimicrobial resistance, (ii) the need for responsible use of antibiotics and (iii) the importance of infection prevention and control measures;

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<sup>1</sup> And, where appropriate, regional economic integration organizations.

(8) to encourage and support research and development, including by academia and through new collaborative and financial models, to combat antimicrobial resistance and promote responsible use of antimicrobials, develop practical and feasible approaches for extending the lifespan of antimicrobial medicines and encourage the development of novel diagnostics and antimicrobial medicines;

(9) to collaborate with the Secretariat in developing and implementing a draft global action plan to combat antimicrobial resistance including antibiotic resistance, which is based on all available evidence and best practices;

(10) to develop antimicrobial resistance surveillance systems in three separate sectors: (i) inpatients in hospitals; (ii) outpatients in all other health care settings and the community; and (iii) animals and non-human usage of antimicrobials;

2. REQUESTS the Director-General:

(1) to ensure that all relevant parts of the Organization, at headquarters, regional and country levels, are actively engaged and coordinated in promoting work on containing antimicrobial resistance, including through the tracking of resource flows for research and development on antimicrobial resistance in the new global health research and development observatory;

(2) to set aside adequate resources for the work in the Secretariat, in line with the Programme budget 2014–2015 and the Twelfth General Programme of Work, 2014–2019;

(3) to strengthen the tripartite collaboration between FAO, OIE and WHO for combating antimicrobial resistance in the spirit of the “One Health” approach;

(4) to explore with the United Nations Secretary-General options for a high-level initiative, including a high-level meeting, to increase political awareness, engagement and leadership on antimicrobial resistance;

(5) to develop a draft global action plan to combat antimicrobial resistance, including antibiotic resistance, which addresses the need to ensure that all countries, especially low- and middle-income countries, have the capacity to combat antimicrobial resistance and which takes into account existing action plans and all available evidence and best practice as well as the recommendations of WHO’s Strategic Technical Advisory Group on antimicrobial resistance and the WHO policy package to combat antimicrobial resistance, which asks Member States:

(a) to commit to a comprehensive, financed national plan with accountability and civil society engagement;

(b) to strengthen surveillance and laboratory capacity;

(c) to ensure uninterrupted access to essential medicines of assured quality;

(d) to regulate and promote rational use of medicines, including in animal husbandry, and ensure proper patient care;

(e) to enhance infection prevention and control;

- (f) to foster innovation and research and development for new tools;
- (6) to apply a multisectoral approach to inform the drafting of the global action plan, by consulting Member States<sup>1</sup> as well as other relevant stakeholders, especially other multilateral stakeholders, such as FAO and OIE;
- (7) to submit to the Sixty-eighth World Health Assembly, through the Executive Board at its 136th session, a draft global action plan to combat antimicrobial resistance, including antibiotic resistance, together with a summary report on progress made in implementing the other aspects of this resolution.

(Eleventh meeting, 24 January 2014)

**EB134.R14      Health intervention and technology assessment in support of universal health coverage**

The Executive Board,

Having considered the report on health intervention and technology assessment in support of universal health coverage,<sup>2</sup>

RECOMMENDS to the Sixty-seventh World Health Assembly the adoption of the following resolution:<sup>3</sup>

The Sixty-seventh World Health Assembly,

Having considered the report on health intervention and technology assessment in support of universal health coverage;

Recalling resolutions WHA52.19 on the revised drug strategy, WHA58.33 on sustainable health financing, universal coverage and social health insurance, WHA60.16 on progress in the rational use of medicines, WHA60.29 on health technologies, WHA63.21 on WHO's role and responsibilities in health research, and WHA64.9 on sustainable health financing structures and universal coverage;

Recognizing the importance of evidence-based policy development and decision-making in health systems, including decisions on resource allocation, service system designs and translation of policies into practice, as well as reaffirming WHO's roles and responsibilities in provision of support to strengthen information systems and health research capacity, and their utilization in Member States;

Noting that the efficient use of resources is a crucial factor in the sustainability of health systems' performance, especially when significant increases in access to essential medicines, including generic medicines, to medical devices and procedures, and to other health care interventions for promotion, prevention, diagnosis and treatment, rehabilitation and palliative care are pursued by Member States, as they move towards universal health coverage;

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<sup>1</sup> And, where applicable, regional economic integration organizations.

<sup>2</sup> Document EB134/30.

<sup>3</sup> See Annex 5 for the financial and administrative implications for the Secretariat of the adoption of the resolution.



Noting that *The world health report 2010*<sup>1</sup> indicates that as much as 40% of spending on health is being wasted and that there is, therefore, an urgent need for systematic, effective solutions to reduce such inefficiencies and to enhance the rational use of health technology;

Acknowledging the critical role of independent health intervention and technology assessment, as multidisciplinary policy research, in generating evidence to inform prioritization, selection, introduction, distribution, and management of interventions for health promotion, disease prevention, diagnosis and treatment, and rehabilitation and palliation;

Emphasizing that with rigorous and structured research methodology and transparent and inclusive processes, assessment of medicines, vaccines, medical devices and equipment, and health procedures, including preventive intervention, could help to address the demand for reliable information on the safety, efficacy, quality, appropriateness, cost-effectiveness and efficiency dimensions of such technologies to determine if and when they are integrated into particular health interventions and systems;

Concerned that the capacity to assess, research and document the public health, economic, organizational, social, legal and ethical implications of health interventions and technologies is inadequate in most developing countries, resulting in inadequate information to guide rational policy, and professional decisions and practices;

Recognizing the importance of strengthened national capacity, regional and international networking, and collaboration on health intervention and technology assessment to promote evidence-based health policy,

1. URGES Member States:<sup>2</sup>

- (1) to encourage the systematic utilization of independent health intervention and technology assessment in support of universal health coverage to inform policy decisions, including priority-setting, selection, procurement supply system management and use of health interventions and/or technologies, as well as the formulation of sustainable financing benefit packages, medicines, benefits management including pharmaceutical formularies, clinical practice guidelines and protocols for public health programmes;
- (2) to consider, in addition to the use of established and widely agreed methods, developing as appropriate national methodological and process guidelines and monitoring systems for health intervention and technology assessment in order to ensure the transparency, quality and policy relevance of related assessments and research;
- (3) to further consolidate and promote health intervention and technology assessment within national frameworks, such as those for health system research, health professional education, health system strengthening and universal health coverage;
- (4) to consider strengthening national capacity for regional and international networking, developing national know-how, avoiding duplication of efforts and achieving better use of resources;

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<sup>1</sup> The world health report 2010. Health systems financing: the path to universal coverage. Geneva: World Health Organization; 2010.

<sup>2</sup> And, where applicable, regional economic integration organizations.

(5) to consider also collaborating with other Member States' health organizations, academic institutions, professional associations and other key stakeholders in the country or region in order to collect and share information and lessons learnt so as to formulate and implement national strategic plans concerning capacity-building for and introduction of health intervention and technology assessment, and summarizing best practices in transparent, evidence-informed health policy and decision-making;

(6) to identify gaps with regard to promoting and implementing evidence-based health policy, as well as improving related information systems and research capacity, and considering seeking technical support and exchanging information and sharing experiences with other Member States, regional networks and international entities, including WHO;

(7) to develop and improve the collection of data on health intervention and technology assessment, training relevant professionals, as appropriate, so as to improve assessment capacity;

2. REQUESTS the Director-General:

(1) to assess the status of health intervention and technology assessment in Member States in terms of methodology, human resources and institutional capacity, governance, linkage between health intervention and technology assessment units and/or networks with policy authorities, utilization of assessment results, and interest in and impediments to strengthening capacity;

(2) to raise awareness of, and to foster knowledge and encourage the practice of health intervention and technology assessment and its uses in evidence-based decision-making among national policy-makers and other stakeholders, by drawing best practices from the operation, performance and contribution of competent research institutes and health intervention and technology assessment agencies and programmes, and sharing such experiences with Member States through appropriate channels and activities, including global and regional networks and academic institutions;

(3) to integrate health intervention and technology assessment concepts and principles into the relevant strategies and areas of work of WHO, including, but not limited to, those on universal health coverage, including health financing, access to and rational use of quality-assured medicines, vaccines and other health technologies, the prevention and management of noncommunicable and communicable diseases, mother and child care, and the formulation of evidence-based health policy;

(4) to provide technical support to Member States, especially low-income countries, relevant intergovernmental organizations and global health partners, in order to strengthen capacity for health intervention and technology assessment, including, when appropriate, the development and use of global guidance on methods and processes based on internationally agreed practices;

(5) to ensure adequate capacity at all levels of WHO, utilizing its networks of experts and collaborating centres, as well as other regional and international networks, in order to address the demand for support to facilitate evidence-based policy decisions in Member States;

(6) to support exchange of information, sharing of experiences and capacity-building in health intervention and technology assessment through collaborative mechanisms and

networks at global, regional and country levels, as well as ensuring that these partnerships are active, effective and sustainable;

(7) to report on progress in the implementation of this resolution, through the Executive Board, to the Sixty-ninth World Health Assembly.

(Twelfth meeting, 24 January 2014)

**EB134.R15 Follow-up of the Recife Political Declaration on Human Resources for Health: renewed commitments towards universal health coverage**

The Executive Board,

Having considered the report on follow-up of the Recife Political Declaration on Human Resources for Health: renewed commitments towards universal health coverage,<sup>1</sup>

RECOMMENDS to the Sixty-seventh World Health Assembly the adoption of the following resolution:<sup>2</sup>

The Sixty-seventh World Health Assembly,

Having considered the outcome document of the Third Global Forum on Human Resources for Health (Recife, Brazil, 10–13 November 2013);

Recognizing the leadership role of WHO in human resources for health, and the mandate given in this regard by resolution WHA63.16 on the WHO Global Code of Practice on the International Recruitment of Health Personnel;

Recalling the commitment to attain universal health coverage and the need for an improved health workforce to achieve it;

Reaffirming the importance of the Kampala Declaration and Agenda for Global Action, as well as the WHO Global Code of Practice on the International Recruitment of Health Personnel, and recognizing the need to renew these commitments and take them forward in light of new developments with a view to progressing towards universal health coverage,

1. ENDORSES the call to action in the Recife Political Declaration on Human Resources for Health: renewed commitments towards universal health coverage;
2. WELCOMES the commitments made by Member States in the Recife Political Declaration on Human Resources for Health: renewed commitments towards universal health coverage;
2. URGES Member States<sup>3</sup> to implement, as appropriate, and in accordance with national and subnational responsibilities, the commitments made in the Recife Political Declaration on Human Resources for Health: renewed commitments towards universal health coverage;

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<sup>1</sup> Document EB134/55.

<sup>2</sup> See Annex 5 for the financial and administrative implications for the Secretariat of the adoption of the resolution.

<sup>3</sup> And, where applicable, regional economic integration organizations.

3. REQUESTS the Director General to take into consideration the Recife Political Declaration on Human Resources for Health: renewed commitments towards universal health coverage in the future work of WHO.

(Twelfth meeting, 24 January 2014)

#### **EB134.R16      Access to essential medicines**

The Executive Board,

Having considered the report on access to essential medicines,<sup>1</sup>

RECOMMENDS to the Sixty-seventh World Health Assembly the adoption of the following resolution:<sup>2</sup>

The Sixty-seventh World Health Assembly,

Having considered the report on access to essential medicines;

Noting that WHO's definition of an essential medicine<sup>3</sup> contains the following elements: "Essential medicines are those that satisfy the priority health care needs of the population" and "Essential medicines are selected with due regard to their public health relevance, evidence of efficacy and safety, and comparative cost-effectiveness";

Recalling resolution WHA28.66 on prophylactic and therapeutic substances that relates to the formulation and implementation of medicines policies and pharmaceutical strategies; the Declaration of Alma-Ata in 1978 that recognized the provision of essential medicines as one of the pillars of primary health care, and subsequent resolutions in relation to essential medicines, such as resolution WHA54.11 on the WHO medicines strategy, WHA58.27 on improving the containment of antimicrobial resistance, WHA60.16 on progress in the rational use of medicines, WHA60.20 on better medicines for children, WHA60.29 on health technologies, WHA61.21 on the global strategy and plan of action on public health, innovation and intellectual property, and WHA64.9 on sustainable health financing structures and universal coverage, as well as WHA66.10 in which the Health Assembly endorsed the WHO global action plan for the prevention and control of noncommunicable diseases 2013–2020, and which includes Target (9) on the availability of essential medicines required to treat noncommunicable diseases;

Bearing in mind that the WHO medicines strategy, as set out in the Twelfth General Programme of Work 2014–2019, is based on the principles of evidence-based selection of a limited range of medicines, efficient procurement and distribution systems, affordable prices, and the rational use of medicines in order to promote better management and greater availability of medicines, more cost-effective use of health resources, and higher quality health care;

Considering that the effective implementation of the above principles is of critical importance to improving people's health, progressing towards universal health coverage and achieving the health-related Millennium Development Goals;

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<sup>1</sup> Document EB134/31.

<sup>2</sup> See Annex 5 for the financial and administrative implications for the Secretariat of the adoption of the resolution.

<sup>3</sup> See WHO Technical Report Series, No. 985.

Welcoming WHO's regional actions in support of greater access to – and availability, affordability and rational use of – safe, effective and quality-assured essential medicines, including development of the Regional Office for the Western Pacific Regional Framework for Action on Access to Essential Medicines (2011–2016);

Acknowledging the complexity of the medicines supply chain and the challenges that countries encounter in this regard, the importance of good governance for medicines programmes,<sup>1</sup> and the consequences of the high costs of medicines, which are among the factors that make accessing care and treatment unaffordable;

Aware that shortages of essential medicines are a global problem that has an impact on the care of patients, the causes and implications of which vary from one country to another, and that there is insufficient information to determine the magnitude and specific characteristics of the problem;

Realizing the role of evidence-based clinical treatment guidelines to guide cost-effective treatment practices, the need for reliable and unbiased information to support rational prescribing, and the importance of increased health literacy to support patients and consumers to use medicines wisely;

Noting with concern that despite sustained efforts over a number of decades by Member States, the Secretariat and partners, most low-income countries are still facing a multitude of challenges in improving the availability, affordability and rational use of essential medicines;

Noting that the goal of Member States is to increase access to affordable, safe, effective and quality-assured essential medicines, including as appropriate, through the full use of the flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights in line with the Global Strategy and Plan of Action on Public Health Innovation and Intellectual Property;

Noting that support for research and development is important for the sustainable supply of future essential medicines, to address public health needs,

1. URGES Member States:<sup>2</sup>

- (1) to recognize the need and provide adequate resources, as required, for the development of comprehensive national medicine policies, strengthened pharmaceutical regulatory, procurement and distributions systems and coordinated responses to address the complex and interrelated activities that affect access to essential medicines, in order to improve their availability, affordability, quality and rational use;
- (2) to improve national policies for selection of essential medicines, particularly by using transparent, rigorous, evidence-based processes based on the methods of health technology assessment in selecting medicines for inclusion in the national essential medicines lists according to each country's health needs and priorities;

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<sup>1</sup> In WHO's assessment instrument for measuring transparency in the public pharmaceutical sector (document WHO/EMP/MAR/2009.4), "good governance" refers to the formulation and implementation of appropriate policies and procedures that ensure the effective, efficient and ethical management of pharmaceutical systems, in particular medicines regulatory systems and medicine supply systems, in a manner that is transparent, accountable, follows the rule of law and minimizes corruption.

<sup>2</sup> And, where applicable, regional economic integration organizations.

- (3) to encourage and support research on health systems regarding the procurement, supply and rational use of essential medicines;
- (4) to promote collaboration and strengthen the exchange of information on best practices in the development, implementation and evaluation of medicine policies and strategies, that enhance access to affordable, safe, effective and quality-assured essential medicines;
- (5) to place greater emphasis on medicines for children and to promote the availability, affordability, quality and safety of essential medicines for children through the development and manufacture of appropriate paediatric formulations and to facilitate market access to these medicines;
- (6) to improve the education and training of health care professionals in order to support the implementation of national policies and strategies in relation to essential medicines, and to develop and implement evidence-based clinical practice guidelines and other interventions for the rational use of essential medicines;
- (7) to strengthen the engagement with the general public and civil society to increase awareness and knowledge of essential medicines and public involvement in enhancing access to and the rational use of these medicines;
- (8) to identify key barriers to access to essential medicines and to develop strategies to address these barriers, making use of WHO's tools<sup>1</sup> and guidance as appropriate;
- (9) to establish or strengthen, as appropriate, systems to monitor the availability, affordability and utilization of safe, effective and quality-assured essential medicines in public and private health facilities;
- (10) to systematize information collection and strengthen monitoring mechanisms, in order to better detect and understand the causes of essential medicines shortages, and to develop strategies to prevent and mitigate the associated problems and risk caused by shortages;
- (11) to consider, as appropriate, adapting national legislation in order to make full use of the provisions contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including the flexibilities recognized by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health and other WTO instruments related to that agreement, in order to promote access to essential medicines, in line with the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property;

## 2. REQUESTS the Director-General:

- (1) to urge Member States to recognize the importance of effective national medicines policies, and their implementation under good governance, in order to ensure equity of access to affordable, safe, effective and quality-assured essential medicines and their rational use in practice;

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<sup>1</sup> Including but not limited to: pharmaceutical sector country profiles, the assessment instrument for measuring transparency in the public pharmaceutical sector, the WHO/Health Action International tool for measuring medicine prices, availability, affordability and price components, and guidance on how to investigate drug use in health facilities.

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- (2) to facilitate and support the exchange of information and collaboration among Member States on best practices in the development and implementation of medicines policies;
  - (3) to support Member States in sharing best practices in the selection of essential medicines, and facilitating collaboration between the Secretariat and Member States in developing processes for the selection of medicines for national essential medicines lists consistent with the evidence-based methods used for updating the WHO Model List of Essential Medicines;
  - (4) to support Member States in building capacity for the evidence-based selection of essential medicines, the development and dissemination of, and adherence to, clinical practice guidelines and the promotion of other strategies for the rational use of affordable, safe, effective and quality-assured essential medicines by health care professionals and the public;
  - (5) to support Member States in developing and implementing their national medicines policies and supply systems especially with regard to regulation, financing, selection, procurement, distribution, pricing, reimbursement and use, in order to increase their efficiency and ensure the access to safe, effective and quality-assured essential medicines, including high price essential medicines;
  - (6) to support Member States in systematizing information collection and strengthening monitoring mechanisms, in order to better detect and understand the causes of essential medicines shortages, and in developing strategies to prevent and mitigate the associated problems and risk caused by shortages;
  - (7) to urge Member States to expedite progress towards the achievement of the Millennium Development Goals and universal health coverage by, inter alia, implementing national medicines policies for improving access to affordable, safe, effective, and quality-assured essential medicines;
  - (8) to provide, as appropriate, upon request, in collaboration with other competent international organizations, technical support, including, where appropriate, to policy processes to Member States that intend to make use of the provisions contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including the flexibilities recognized by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health and other WTO instruments related to that Agreement, in order to promote access to essential medicines, in accordance with the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property;
  - (9) to report to the Sixty-ninth World Health Assembly, through the Executive Board, on the implementation of this resolution.

(Thirteenth meeting, 25 January 2014)

**EB134.R17      Regulatory system strengthening for medical products**

The Executive Board,

Having considered the report on regulatory system strengthening,<sup>1</sup>

RECOMMENDS to the Sixty-seventh World Health Assembly the consideration and adoption of the following resolution:<sup>2</sup>

The Sixty-seventh World Health Assembly,

Welcoming the efforts of the Director-General, and recognizing the pivotal role that WHO plays in supporting countries in strengthening their regulatory systems of medical products for human use,<sup>3</sup> and in promoting equitable access to quality, safe, efficacious, and affordable medical products;

Recalling the Constitution of the World Health Organization, which affirms that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition;

Recalling also United Nations General Assembly resolution 67/81 on global health and foreign policy, which, inter alia, recognized the importance of universal coverage in national health systems, especially through primary health care and social protection mechanisms, in the provision of access to health services for all, in particular for the poorest segments of the population;

Recalling further resolutions WHA45.17, WHA47.17, WHA52.19, WHA54.11, WHA59.24, WHA63.12, and WHA65.19, all of which encompass aspects of the need to promote the quality, safety, efficaciousness and affordability of medicines, including blood products;

**[Reaffirming resolution WHA65.19, which establishes a new Member State mechanism for international collaboration, from a public health perspective, to prevent and control substandard/spurious/false-labelled/falsified/counterfeit medical products and to promote access to affordable, safe and quality medical products;]**

Recognizing that effective regulatory systems are an essential component of health system strengthening and contribute to better public health outcomes, that regulators are an essential part of the health workforce, and that inefficient regulatory systems themselves can be a barrier to access to safe, effective and quality medical products;

Recognizing also that effective regulatory systems are necessary for implementing universal health coverage, responding to the dual burden of infectious and noncommunicable diseases, and achieving Millennium Development Goal 4 (Reduce child mortality) Goal 5 (Improve maternal health) and Goal 6 (Combat HIV/AIDS, malaria and other diseases);

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<sup>1</sup> Document EB134/29.

<sup>2</sup> See Annex 5 for the financial and administrative implications for the Secretariat of the adoption of the resolution.

<sup>3</sup> For the purpose of this resolution, medical products include medicines, vaccines, diagnostics and medical devices.



Aware that health systems need to promote access to essential medical products and that, in order to ensure universal access to health care, rational use of medicines and the sustainability of health systems, urgent action is needed by the international community, Member States and relevant actors in health systems;

Very concerned by the impact on patients of medical products of compromised quality, safety and efficacy, in terms of poisoning, inadequate or no treatment, contributions to drug resistance, the related economic burden, and erosion of public trust in the health system;

**[Aware of the regulatory challenges presented by ever-increasing complexities of medical product global supply chains;]**

Emphasizing WHO's role in strengthening regulatory systems for medical products from a public health perspective, and in supporting national drug regulatory authorities and relevant regional bodies in this area, and in particular in developing countries;

Recalling the WHO global strategy and plan of action on public health, innovation and intellectual property, in particular element three, which calls for establishing and strengthening regulatory capacity in developing countries as one effective policy for building and improving innovative capacity, and element six, which promotes establishing and strengthening mechanisms to improve ethical review and regulate the quality, safety and efficacy of health products and medical devices;

Noting with appreciation the many national and regional efforts to strengthen regulatory capacity (including through a variety of models), improve regulatory coherence and convergence among regulatory authorities, and enhance good governance, including transparency in decision-making, leading to the improved availability of quality, safe, efficacious and affordable medical products, such as the European Union regulatory framework for medical products, work under way in PAHO following its 2010 resolution CD50.R9, the African Medicines Regulatory Harmonization Initiative, and the regulatory harmonization and cooperation work in ASEAN;

**[Also noting with appreciation the ongoing collaboration between some national regulatory authorities, including at the global level, in setting standards, including the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use among others, and encouraging a continued emphasis of effort in strengthening regulatory systems in accordance with WHO principles and guidelines;]**

Recognizing the significant investments made in the procurement of medicines through global health initiatives, national health budgets, and, in particular, the essential role of WHO's prequalification programme and national regulatory systems in assuring the safety, quality and efficacy of these medical products;

Recalling the WHO good clinical practices that focus on the protection of human research subjects;

Recalling also WHO's ongoing reform agenda and welcoming in this regard the establishment in November 2012 of the Health Systems and Innovation cluster,

1. URGES Member States:<sup>1</sup>

- (1) to strengthen national regulatory systems by, as appropriate:
  - (a) undergoing self-evaluations, including with WHO support, to identify the strengths and opportunities for improvement in regulatory system functions, as a first step towards formulating plans for regulatory systems strengthening, including through WHO-coordinated institutional development plans;
  - (b) collecting data on regulatory system performance to enable analysis and benchmarking for improved systems in the future;
  - (c) developing strong legal foundations and political leadership to underpin a regulatory system with a clear focus on patient safety and transparency in decision-making;
  - (d) identifying and developing a core set of regulatory functions to meet country and/or regional needs, such as market control and postmarket surveillance;
  - (e) developing needed competencies as an integral part of, although not limited to, the health workforce, and encouraging the development of the regulatory field as a profession;
  - (f) **[implementing relevant guidance and science-based outputs of international regulatory harmonization and convergence efforts such as, where applicable, the Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use;]**
  - (g) **[implementing strategies to address the increasing complexities of global supply chains;]**
- (2) to engage in global, regional and subregional networks of national regulatory authorities, as appropriate, recognizing the importance of collaboration to pool regulatory capacities to promote greater access to quality, safe, efficacious and affordable medical products;
- (3) to promote international cooperation, as appropriate, for convergence and information sharing, including through electronic platforms;
- (4) to support regulatory systems for medical products with appropriate funding as an essential component of the health system;
- (5) to support regulatory system strengthening as an essential prerequisite to the development or expansion of local or regional production of quality, safe and efficacious medical products;
- (6) to achieve access to and rational use of quality, safe, efficacious and affordable essential medicines, noting the growing emergence of resistance, and as a foundation for achieving broader access to quality, safe, efficacious and affordable medical products;

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<sup>1</sup> And, where applicable, regional economic integration organizations.

(7) to support WHO's institutional capacity relating to promoting access to and rational use of quality, safe, efficacious and affordable medical products in the context of universal health coverage;

(8) **[to support WHO in its efforts to strengthen its prequalification programmes, including exploring modalities in consultation with Member States<sup>1</sup> for improved sustainability of this critical programme, [while also focusing on supporting national and regional initiatives to improve regulatory capacity for medical products][focusing on achieving longer term objectives of developing national regulatory authority capacity among Member States];]**

(9) to identify the need to strengthen regulatory system capacity, collaboration and convergence in the technically complex areas where substantial gaps may still exist, such as the regulation of biotherapeutic products, blood products, and in vitro diagnostics;

2. REQUESTS the Director-General:

(1) to continue to support countries in the area of regulatory system strengthening, including by developing appropriate norms and standards[, **taking into account the standards created by existing regional and international initiatives**]; continue to evaluate national regulatory systems; continue to apply and improve WHO evaluation tools; continue to generate and analyse evidence of regulatory systems performance; continue to facilitate the formulation and implementation of institutional development plans; and continue to provide technical support to national regulatory authorities and governments;

(2) to ensure that all relevant parts of the Organization, at all levels, are actively engaged and coordinated in the carrying out of WHO's mandate pertaining to regulatory system strengthening as an integrated part of health system development, recognizing that WHO's support in this critical area, particularly for developing countries, may be required, as appropriate, well into the future;

(3) to prioritize support for establishing and strengthening regional and subregional networks of regulatory authorities, as appropriate, including strengthening areas of regulation of health products that are the least developed, such as regulation of medical devices, including diagnostics;

(4) to promote the greater participation of Member States in existing international and regional initiatives for collaboration, harmonization and convergence in accordance with WHO principles and guidelines;

(5) **[to strengthen the integration and coherence among WHO's prequalification programmes as an aid to assuring safe supply of quality medical products, engaging with Member States in the further refinement and improvement of the global prequalification model, while in parallel supporting the development of functional national and regional regulatory bodies and networks, leading to more global participation in the global prequalification programme;]**

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<sup>1</sup> And, where applicable, regional economic integration organizations.

(6) to increase support for and recognition of the significant role of the International Conference of Drug Regulatory Authorities in promoting the exchange of information and collaborative approaches among drug regulatory authorities, and as a resource to guide and facilitate further development of, and regulatory harmonization and convergence among, these authorities;

(7) to raise awareness of the importance of effective regulatory systems within the health system context;

(8) to increase support and guidance for strengthening the capacity to regulate increasingly complex biological products with the focus on biotherapeutic products, blood products and associated in vitro diagnostics, and, where appropriate, on new medicines for human use based on gene therapy, somatic-cell therapy and tissue engineering;

(9) to report to the Seventieth and Seventy-second World Health Assemblies, through the Executive Board, on progress in the implementation of this resolution.

(Thirteenth meeting, 25 January 2014)

## **EB134.R18      Hepatitis**

The Executive Board,

Having considered the report on hepatitis,<sup>1</sup>

RECOMMENDS to the Sixty-seventh World Health Assembly the consideration and adoption of the following resolution:<sup>2</sup>

The Sixty-seventh World Health Assembly,

Reaffirming resolution WHA63.18, adopted in 2010 by the World Health Assembly, which recognized viral hepatitis as a global public health problem and the need for governments and populations to take action to prevent, diagnose and treat viral hepatitis, and that called upon WHO to develop and implement a comprehensive global strategy to support these efforts, and expressing concern at the slow pace of implementation;

Recalling also resolution WHA45.17 on immunization and vaccine quality, which urged Member States to include hepatitis B vaccines in national immunization programmes, and concerned that currently the global hepatitis B vaccine coverage for infants is estimated at 75% and is therefore below the 90% global target;

Recalling further resolution WHA61.21, which adopted the global strategy and plan of action on public health innovation and intellectual property;

Noting with deep concern that viral hepatitis is now responsible for 1.4 million deaths every year (compared to 1.5 million deaths from HIV/AIDS and 1.2 million deaths from each of malaria and tuberculosis), that around 500 million people are currently living with viral hepatitis

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<sup>1</sup> Document EB134/36.

<sup>2</sup> See Annex 5 for the financial and administrative implications for the Secretariat of the adoption of the resolution.

and some 2000 million have been infected with hepatitis B virus, and considering that most people with chronic hepatitis B or C are unaware of their infection and are at serious risk of developing cirrhosis or liver cancer, contributing to global increases in both of those chronic diseases;

Also noting that millions of acute infections with hepatitis A virus and hepatitis E virus occur annually and result in tens of thousands of deaths almost exclusively in lower- and middle-income countries;

Considering that while hepatitis C is not preventable by vaccination, current treatment regimens offer high cure rates that are expected to further improve with upcoming new treatments; and that although hepatitis B is preventable with a safe and effective vaccine, there are 240 million people living with hepatitis B virus infection and available effective therapies could prevent cirrhosis and liver cancer among many of those infected;

Expressing concern that preventive measures are not universally implemented and that equitable access to and availability of quality, effective, affordable and safe diagnostics and treatment regimens for both hepatitis B and C are lacking in many parts of the world, particularly in developing countries;

Recognizing the role of health promotion and prevention in the fight against viral hepatitis, and emphasizing the importance of strengthening vaccination strategies as high impact and cost-effective actions for public health;

Noting with concern that globally the birth dose coverage rate with hepatitis B vaccine remains unacceptably low;

Acknowledging also that, in Asia and Africa, hepatitis A and E continue to cause major outbreaks while a safe effective hepatitis A vaccine has been available for nearly two decades, and that hepatitis E vaccine candidates have been developed but not yet certified by WHO, and that lack of basic hygiene and sanitation promotes the risks of hepatitis A virus and hepatitis E virus transmission and most vulnerable populations do not have that access to those vaccines;

Taking into account that injection overuse and unsafe practices account for a substantial burden of death and disability worldwide, with an estimated 2 million hepatitis B virus infections and 500 000 hepatitis C virus infections in 2010;

Recognizing the need for safe blood to be available to blood recipients, as established by resolution WHA28.72 on utilization and supply of human blood and blood products, in which the World Health Assembly recommended the development of national public services for blood donation, and in resolution WHA58.13, in which the World Health Assembly agreed to the establishment of an annual World Blood Donor Day, considering that one of the main routes of transmission of hepatitis B virus and hepatitis C virus is parenteral;

Further recognizing the need to strengthen health systems and integrate collaborative approaches and synergies between prevention and control measures for viral hepatitis and those for infectious diseases such as HIV and other related sexually transmitted and blood-borne infections and other mother-to-child transmitted diseases, as well as for cancer and noncommunicable disease programmes;

Noting that hepatitis B virus, and particularly hepatitis C virus, disproportionately impact upon people who inject drugs, and that of the 16 million people who inject drugs around the

world, an estimated 10 million are living with hepatitis C virus infection and 1.2 million are living with hepatitis B virus infection;

**[Recalling United Nations General Assembly resolution 65/277, subparagraph 59(h), and that the nine core interventions<sup>1</sup> mentioned in the WHO/UNODC/UNAIDS Technical Guide for countries to set targets for universal access to HIV prevention, treatment and care for injecting drug users are important components for both hepatitis B virus and hepatitis C virus prevention, diagnosis and treatment, and that access to those remain limited or absent in many countries of high hepatitis B virus and hepatitis C virus burden;]**

Cognizant of the fact that 4–5 million people living with HIV are coinfecting with hepatitis C virus and more than 3 million are coinfecting with hepatitis B virus, which has become a major cause of disability and mortality amongst those taking antiretroviral therapy;

Taking into account that viral hepatitis is a major problem within indigenous communities in some countries;

Welcoming the development by WHO of a global strategy, within a health systems approach, on the prevention and control of viral hepatitis infection;<sup>2</sup>

Considering that most Member States lack adequate surveillance systems for viral hepatitis to enable them to take evidence-based policy decisions;

Taking into account that a periodic evaluation of implementation of the WHO strategy is crucial to monitor the global response to viral hepatitis and that the process was initiated with the 2013 publication of the Global policy report on the prevention and control of viral hepatitis in WHO Member States;

Acknowledging the need to reduce liver cancer mortality rates and that viral hepatitis is responsible for 78% of cases of primary liver cancer, and welcoming the inclusion of an indicator on hepatitis B vaccination in the comprehensive global monitoring framework adopted in resolution WHA66.10 on the Follow-up to the Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases;

Acknowledging the need to fight and to eliminate stigma and discrimination against people living with or affected by viral hepatitis and determined to protect and safeguard their human rights,

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<sup>1</sup> Needle and syringe programmes; opioid substitution therapy and other drug dependence treatment; HIV testing and counselling; antiretroviral therapy; prevention and treatment of sexually transmitted infections; condom programmes for injecting drug users and their sexual partners; targeted information, education and communication for injecting drug users and their sexual partners; vaccination, diagnosis and treatment of viral hepatitis; and prevention, diagnosis and treatment of tuberculosis.

<sup>2</sup> Prevention & Control of Viral Hepatitis Infection: Framework for Global Action. Geneva: World Health Organization; 2012.

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1. URGES Member States:<sup>1</sup>

- (1) to develop and implement coordinated multisectoral national strategies for preventing, diagnosing, and treating viral hepatitis based on the local epidemiological context;
- (2) to enhance actions related to health promotion and prevention of viral hepatitis, while stimulating and strengthening immunization strategies, including for hepatitis A, based on the local epidemiological context;
- (3) to promote the involvement of civil society in all aspects of preventing, diagnosing and treating viral hepatitis;
- (4) to put in place an adequate surveillance system for viral hepatitis in order to support decision-making on evidence-based policy;
- (5) to strengthen the system for collection of blood from low-risk, voluntary, non-remunerated donors, for quality-assured screening of all donated blood for HIV, hepatitis B, hepatitis C and syphilis, and for good transfusion practices to ensure patient safety;
- (6) to strengthen the system for quality-assured screening for HIV, hepatitis B, hepatitis C and syphilis, of all donors of tissues and organs;
- (7) to reduce the prevalence of chronic hepatitis B infection as proposed by WHO regional committees, in particular by enhancing efforts to prevent perinatal transmission through the delivery of the birth dose of hepatitis B vaccine;
- (8) to strengthen measures for the prevention of hepatitis A and E, in particular food and drinking-water safety and hygiene promotion;
- (9) to strengthen infection control in health care settings through all necessary measures to prevent the reuse of equipment designed only for single use, and cleaning and either high-level disinfection or sterilization, as appropriate, of multi-use equipment;
- (10) to include hepatitis B vaccine for infants, where appropriate, in national immunization programmes, working towards full coverage;
- (11) to make special provision in policies for the equitable access to prevention, diagnosis and treatment for populations affected by viral hepatitis, particularly indigenous people, migrants and vulnerable groups, where applicable;
- (12) to consider, as necessary, national legislative mechanisms for the use of the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights in order to promote access to specific pharmaceutical products;<sup>2</sup>

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<sup>1</sup> And, where applicable, to regional economic integration organizations.

<sup>2</sup> The WTO General Council in its Decision of 30 August 2003 (i.e. on Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health) decided that “‘pharmaceutical product’ means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration. It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included.”

(13) to consider, whenever necessary, the use of administrative and legal means in order to promote access to preventive, diagnostic and treatment technologies against viral hepatitis;

**(14) [to establish, as appropriate, national harm reduction policies based on national legislation, policies and procedures, while using WHO standards;<sup>1</sup>]**

[or]

**(14) [to implement, in line with United Nations General Assembly resolution 65/277, subparagraph 59(h), [harm reduction programmes] taking into account the nine core interventions included in the WHO /UNODC/UNAIDS Technical Guide for countries to set targets for universal access to HIV prevention, treatment and care for injecting drug users when establishing policies for the prevention, control and treatment of viral hepatitis, taking into account the domestic context and jurisdictional responsibility;]**

(15) to aim to transition by 2017 to the exclusive use, where appropriate, of WHO prequalified or equivalent safety engineered injection devices including reuse-prevention syringes and sharp injury prevention devices for therapeutic injections and develop related national policies;

(16) to review, as appropriate, policies, procedures and practices associated with stigma and discrimination, including the denial of employment, training and education, as well as travel restrictions, against people living with and affected by viral hepatitis, or impairing their full enjoyment of the highest attainable standard of health;

2. REQUESTS the Director-General:

(1) to provide the necessary technical support to enable countries to develop robust national viral hepatitis prevention, diagnosis and treatment strategies with time-bound goals;

(2) to develop specific guidelines on adequate, effective and affordable algorithms for diagnosis in developing countries;

(3) in consultation with Member States, to develop a system for regular monitoring and reporting on the progress in viral hepatitis prevention, diagnosis and treatment;

(4) to provide technical guidance on cost-effective ways to integrate the prevention, testing, care and treatment of viral hepatitis into existing health care systems and make best use of existing infrastructure and strategies;

(5) to work with national authorities, upon their request, to promote comprehensive, equitable access to prevention, diagnosis and treatment for viral hepatitis, with particular attention to needle and syringe programmes and opioid substitution therapy or other evidence-based drug treatments for people who inject drugs, in national plans, taking into consideration national policy context and procedures and to support countries, upon request, to implement these measures;

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<sup>1</sup> WHO/UNODC/UNAIDS Technical guide for countries to set targets for universal access to HIV prevention, treatment and care for injecting drug users. Geneva: World Health Organization; 2009.



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- (6) to provide technical guidance on prevention of transfusion-transmitted hepatitis B and C through safe donation from low-risk, voluntary, non-remunerated donors, counselling, referral and treatment of infected donors, and effective blood screening;
  - (7) to examine the feasibility of and strategies needed for the elimination of hepatitis B and hepatitis C with a view to potentially setting global targets;
  - (8) to estimate global, regional and domestic economic impact and burden of viral hepatitis in collaboration with Member States and relevant organizations, taking into due account potential and perceived conflicts of interest;
  - (9) to support Member States with technical assistance in the use of trade-related aspects of intellectual property rights flexibilities when needed, in accordance with the global strategy and plan of action on public health, innovation and intellectual property;
  - (10) to lead a discussion and work with key stakeholders to facilitate equitable access to quality, effective, affordable and safe hepatitis B and C treatments and diagnostics;
  - (11) to assist Member States to ensure equitable access to quality, effective, affordable and safe hepatitis B and C treatments and diagnostics, in particular in developing countries;
  - (12) to maximize synergies between viral hepatitis prevention, diagnosis and treatment programmes and ongoing work to implement the WHO global action plan for the prevention and control of noncommunicable diseases 2013–2020;
  - (13) to report to the Sixty-ninth World Health Assembly, or earlier if needed, through the Executive Board, on the implementation of this resolution;
3. CALLS upon all relevant United Nations funds, programmes, specialized agencies and other stakeholders:
- (1) to include prevention, diagnosis and treatment of viral hepatitis in their respective work programmes and work in close collaboration;
  - (2) to identify and disseminate mechanisms to support countries in the provision of sustainable funding for the prevention, diagnosis and treatment of viral hepatitis.

(Thirteenth meeting, 25 January 2014)

**EB134.R19      Access to biotherapeutic products and ensuring quality, safety and efficacy**

The Executive Board,

Having considered the report on regulatory system strengthening,<sup>1</sup>

RECOMMENDS to the Sixty-seventh World Health Assembly the consideration and adoption of the following resolution:<sup>2</sup>

The Sixty-seventh World Health Assembly,

Recalling the WHO Constitution, which affirms that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition;

Noting with particular concern that for millions of people, the right to the enjoyment of the highest attainable standard of physical and mental health, including access to medicines, remains a distant goal, that especially for children and those living in poverty, the likelihood of achieving this goal is becoming increasingly remote, that millions of people are driven below the poverty line each year because of catastrophic out-of-pocket payments for health care, and that excessive out-of-pocket payments can discourage the impoverished from seeking or continuing care;

Recalling resolution WHA55.14 on ensuring accessibility of essential medicines, which recognizes “the responsibility of Member States to support solid scientific evidence, excluding any biased information or external pressures that may be detrimental to public health”;

Further recalling that resolution WHA55.14 urged Member States, inter alia, “to reaffirm their commitment to increasing access to medicines, and to translate such commitment into specific regulation within countries, especially enactment of national drug policies and establishment of lists of essential medicines based on evidence and with reference to WHO’s model list into actions designed to promote policy for, access to, and quality and rational use of, medicines within national health systems”;

Considering that one of the objectives of pharmaceutical regulation is the assurance of the quality, safety and efficacy of pharmaceutical products through the regulatory processes of authorization, vigilance and monitoring;

Considering also that national pharmaceutical regulation should contribute to the performance and sustainability of health systems and the general welfare of society;

Considering that an update of the norms and standards applicable to medicines is required in the light of advances made in biotechnology and the new generation of medicines introduced as a result, in order to ensure the entry into the market of medicines that are affordable, safe, efficacious, of quality and accessible in a timely and adequate fashion;

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<sup>1</sup> Document EB134.29.

<sup>2</sup> See Annex 5 for the financial and administrative implications for the Secretariat of the adoption of the resolution.

Recognizing that the use of such medicines has a positive impact on morbidity and mortality rates and that, while there are multiple barriers to access, their high cost affects the sustainability of health systems and could in many cases affect access to them;

**[Noting that WHO Expert Committee on Biological Standardization guidelines of 2009 on evaluation of similar biotherapeutic products and that the placing on the market of these types of products is expected to significantly increase;]**

Conscious that similar biotherapeutic products could be more affordable and offer better access to treatments of biological origin, while ensuring quality, safety and efficacy;

1. URGES Member States:<sup>1</sup>

(1) to develop or strengthen, as appropriate, national regulatory assessment and authorization frameworks, with a view to meeting the public health needs for biotherapeutic products, and in particular similar biotherapeutic products;

**[(2) to ensure that a solid, scientifically-based regulatory review process for reviewing, approving, and monitoring reference biotherapeutic products has been conducted before embarking on the review and approval of similar biotherapeutic products;]**

(3) to work to ensure that the introduction of new national regulations, where appropriate, does not constitute a barrier to access to quality, safe, efficacious and affordable similar biotherapeutic products;

2. REQUESTS the Director-General:

(1) to support Member States in strengthening their capacity in the area of the health regulation of biotherapeutic products and in particular similar biotherapeutic products;

(2) to support, as appropriate, the development of national regulatory frameworks that promote access to quality, safe, efficacious and affordable similar biotherapeutic products;

(3) to encourage and promote cooperation and exchange of information, as appropriate, among Member States in relation to biotherapeutic products, in particular similar biotherapeutic products.

(Fourteenth meeting, 25 January 2014)

## **EB134.R20 Relations with nongovernmental organizations<sup>2</sup>**

The Executive Board,

Having examined the report of its Standing Committee on Nongovernmental Organizations,<sup>3</sup>

1. DECIDES to admit into official relations with WHO the following nongovernmental organizations: the Health on the Net Foundation, the International Council for Commonality in Blood

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<sup>1</sup> And, where applicable, regional economic integration organizations.

<sup>2</sup> See Annex 3 and decision EB134(7).

<sup>3</sup> Document EB134/44.

Banking Automation Inc., IntraHealth International Inc., the Medicines Patent Pool, the Drugs for Neglected Diseases initiative, the American Society for Reproductive Medicine, the International Psycho-Oncology Society, and the International Baby Food Action Network;

2. DECIDES to admit into official relations with WHO the Global Alliance for Improved Nutrition after satisfactory consideration of the information concerning the nature and extent of the links between the Global Alliance for Improved Nutrition and the global food industry, after confirmation of the closure of its Business Alliance, and after clarification of the position of the Global Alliance for Improved Nutrition with regard to its support and advocacy of WHO's nutritional policies, including those on infant feeding and the marketing of complementary foods;

3. DECIDES to discontinue official relations with Collegium Internationale Neuro-Psychopharmacologicum, the Industry Council for Development, International Special Dietary Foods Industries, the Global Forum for Health Research, the International Medical Parliamentarians Organization and the International Conference of Deans of French-Language Faculties of Medicine.

(Fourteenth meeting, 24 January 2014)

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